

According to MPEP § 2173.05(s):

Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Consistent with MPEP § 2173.05(s), incorporation by reference of Figure (1) into claim 3 is necessary because it is not practical to duplicate the entire X-ray diffraction pattern in the claim, and describing the pattern in words is not possible. Applicants also note that incorporation by reference of X-ray diffraction patterns into patent claims is standard practice in the pharmaceutical compound art, as well as in other arts. See, for example, recently granted U.S. Patent Nos. 7,074,928, 7,060,712, 7,015,238, 6,998,503, 6,958,337, and 6,900,221. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 2 and 10 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because they recite the relative term "substantially." According to the Examiner, the term "substantially" is not defined by the claim, the specification does not provide an appropriate standard, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicants respectfully traverse this basis for rejection.

According to MPEP 2173.05(b):

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Applicants submit that, contrary to the Examiner's position, one skilled in the art would ascertain the scope of the claimed subject matter in light of the specification. The paragraph bridging pages 7 and 8 of the instant specification clearly delineates the scope of "substantially free of crystalline forms" recited in claims 2 and 10. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim Rejections – 35 U.S.C. § 102

Claims 1-3 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Tang et al. (*J. China Pharm. Univ.*, 2002; hereinafter "Tang"). According to the Examiner, Tang teaches the claimed amorphous levocetirizine dihydrochloride. Applicants respectfully traverse this rejection.

According to MPEP § 2131:

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 638, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Contrary to the Examiner's position, Tang does not disclose a compound having each and every limitation as set forth in claims 1-3 of the instant application. Claims 1-3 are directed to amorphous levocetirizine dihydrochloride. Although the English portions of Tang apparently disclose the isolation of levocetirizine dihydrochloride, there is no teaching or suggestion that the levocetirizine dihydrochloride is amorphous. Applicants submit that it is error for the Examiner to ignore the element "amorphous." Because Tang does not disclose amorphous levocetirizine dihydrochloride, claims 1-3 cannot be anticipated, and reconsideration of this rejection is respectfully requested.

Claims 1-3 were also rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Pflum et al. (*Organic Process Research & Development*, 2001; hereinafter "Pflum"). According to the Examiner, Pflum teaches the claimed

amorphous levocetirizine dihydrochloride. Applicants respectfully traverse this rejection.

Pflum discloses the synthesis of levocetirizine dihydrochloride, but, as with Tang, does not teach or suggest that the levocetirizine dihydrochloride is amorphous. Again, Applicants submit that it is error for the Examiner to ignore the element "amorphous." Because Pflum does not disclose amorphous levocetirizine dihydrochloride, claims 1-3 are not anticipated, and reconsideration of this rejection is respectfully requested.

Claims 4-16 were further rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Van de Venne et al. (U.S. patent 6,489,329, hereinafter "Van de Venne"). According to the Examiner, Van de Venne teaches compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, the same compositions recited in claims 4-16. Applicants respectfully traverse this rejection.

While Applicants agree that Van de Venne discloses compositions comprising levocetirizine dihydrochloride with one or more pharmaceutically acceptable excipients, they are not the same compositions recited in claims 4-16. Claims 4-16 are directed to a pharmaceutical composition comprising amorphous levocetirizine dihydrochloride and one or more pharmaceutically acceptable excipients. As with Tang and Pflum, there is no teaching or suggestion that the levocetirizine dihydrochloride be amorphous. Applicants note that the Examiner apparently agrees with this conclusion, as the Office Action at page 4 states that "Van de Venne teaches compositions comprising levocetirizine dihydrochloride" (absent the term "amorphous"). Because Van de Venne does not disclose amorphous levocetirizine dihydrochloride, claims 4-16 are not anticipated, and reconsideration of this rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 17 and 18 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Van de Venne. According to the Examiner, Van de Venne teaches compositions comprising levocetirizine dihydrochloride. The Examiner

acknowledges that the reference fails to disclose the claimed moisture content. However, according to the Examiner, it would have been obvious to one skilled in the art at the time of the invention to obtain the claimed composition because obviousness based on similarity of structure and function entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties. Applicants respectfully traverse this rejection.

According to MPEP § 706.02(j):

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Thus, to sustain the rejection of obviousness, the prior art reference must provide all the limitations of claims 17 and 18. Claims 17 and 18 are directed to a pharmaceutical composition comprising amorphous levocetirizine dihydrochloride and one or more pharmaceutically acceptable excipients having a certain moisture content. As discussed above with respect to the § 102 rejection, however, Van de Venne fails to teach or suggest amorphous levocetirizine dihydrochloride, let alone the desirability of the claimed moisture content. Because Van de Venne does not provide all the recited limitations, claims 17 and 18 are not *prima facie* obvious, and reconsideration of this rejection is respectfully requested.

Applicants submit that claims 1-18 are in condition for allowance, early notice of which would be appreciated. No fees are believed due at this time. If,

however, any fees are due, the Commissioner is authorized to charge any such fee to our Deposit Account No. 50-3221.

Respectfully submitted,

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